

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460



OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES  
Antimicrobials Division

February 25, 2005

**SUBJECT: PRODUCT CHEMISTRY REVIEW OF:  
Sterilex Ultra Disinfectant Cleaner Solution 1**

**DP Barcode: D311976**

**Manufacturing-use [] OR**

**Reg. No. Or File Symbol: 63761-I**

**End-use Product [X]**

**TO:** Marshall Swindell/Tony Kish  
PM Team No. 33

**FROM:** Chris Jiang, Chemist  
Product Science Branch  
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**THRU:** Karen P. Hicks, CTT Team Leader  
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**THRU:** Michele Wingfield, Branch Chief  
Product Science Branch  
Antimicrobials Division (7510C)

CJ  
*Karen P. Hicks*  
3/1/05

**Product Formulation from label**

<b>Active Ingredient(s)</b>	<b>% by wt.</b>
n-Alkyl (C <sub>12</sub> 68%, C <sub>14</sub> 32%) ethylbenzyl ammonium chloride	3.00 %
n-Alkyl (C <sub>14</sub> 60%, C <sub>16</sub> 30%, C <sub>12</sub> 5%, C <sub>18</sub> 5%) benzyl ammonium chloride	3.00 %
Hydrogen peroxide	6.30 %

## BACKGROUND:

The registrant is responding to the Agency letter dated October 20, 2004.

## FINDINGS:

1. The concentrations of the active ingredients on the Confidential Statement of Formula (CSF dated 30 November 2004) are consistent with the label declaration.
2. All ingredients are cleared for use in pesticidal products.
3. The certified limits are **acceptable**.
4. The analytical enforcement methods for the active ingredients are **acceptable**.
5. The flammability is **acceptable** as the product does not contain any potentially explosive components.
6. The explodability is **acceptable** as the product does not contain any combustible liquids.
7. The joint study for storage stability and corrosion characteristics is **unacceptable** because the study was not done under GLP compliance. It is also unacceptable because heating the product will get rid of the hydrogen peroxide contained in the product.
8. The miscibility is **acceptable** because the product is not an emulsifiable liquid and is not intended to be diluted with petroleum solvents.
9. The dielectric breakdown voltage is **acceptable** because the product will not be used around electrical equipment.
10. Because the proposed product has public health claims and because the product contains hydrogen peroxide, a one year GLP storage stability study must be submitted to the Agency for review.
11. All of the other data requirements were reviewed and accepted under D307222.

## RECOMMENDATIONS:

1. Product Science Branch of Antimicrobials Division finds this submission in support of the registration of 63761-I to be unacceptable for the reasons discussed in the findings. The registrant must remedy the discrepancies discussed in the findings before registration of this product can proceed.